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09/766,348	01/19/2001	Dewen Qiu	19603/2986 (CRF D-1940B)	7683
7590	11/20/2006		EXAMINER	
Michael L. Goldman NIXON PEABODY LLP Clinton Square P.O. Box 31051 Rochester, NY 14603			KUBELIK, ANNE R	
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**BEFORE THE BOARD OF PATENT APPEALS  
AND INTERFERENCES**

Application Number: 09/766,348  
Filing Date: January 19, 2001  
Appellant(s): QIU ET AL.

**MAILED**  
**NOV 20 2006**  
**GROUP 1600**

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Andrew Gonsalves.  
For Appellant

**EXAMINER'S ANSWER**

This is in response to the appeal brief filed 5 December 2005 appealing from the Office action  
mailed 29 October 2004.

**(1) Real Party in Interest**

A statement identifying by name the real party in interest is contained in the brief.

**(2) Related Appeals and Interferences**

The examiner is not aware of any related appeals, interferences, or judicial proceedings that will directly affect or be directly affected by or have a bearing on the Board's decision in the pending appeal.

**(3) Status of Claims**

The statement of the status of claims contained in the brief is correct.

**(4) Status of Amendments After Final**

The appellant's statement of the status of amendments after final rejection contained in the brief is correct.

**(5) Summary of Claimed Subject Matter**

The summary of claimed subject matter contained in the brief is correct.

**(6) Grounds of Rejection to be Reviewed on Appeal**

The appellant's statement of the grounds of rejection to be reviewed on appeal is substantially correct. The changes are as follows: the present application does not teach the use of non-inducible promoters (including constitutive promoters).

### **NEW GROUND(S) OF REJECTION**

Claims 41-47, 49-54, 58-73, 75-77 and 80-85 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the enablement requirement. The claims contain subject matter that was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention.

### **(7) Claims Appendix**

The copy of the appealed claims contained in the Appendix to the brief is correct.

### **(8) Evidence Relied Upon**

5,850,015	BAUER et al	12-1998
6,174,717	BEER et al	1-2001

Tampakaki et al, Elicitation of hypersensitive cell death by extracellularly targeted HrpZ<sub>Psph</sub> produced in planta, 2000, Molec. Plant Microbe Interact. 13:1366-1374

### **(9) Grounds of Rejection**

The following ground(s) of rejection are applicable to the appealed claims:

a. Claims 41-47, 49-54, 58-73, 75-77 and 80-85 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter that was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

Neither the instant specification nor the originally filed claims appear to provide support for recitation of a “promoter that is not pathogen-inducible” in claims 41, 61 and 75, line 5. The only reference to plant promoters in the specification, on pg 36, line 19, states “various promoters including pathogen-induced promoters”.

Thus, at the time of filing, the only promoters contemplated were pathogen-induced promoters or promoters in general, which included pathogen-induced ones. Promoters other than pathogen-induced ones as a class were not part of the originally filed invention.

Thus, such a recitation constitutes new matter.

#### **NEW GROUND(S) OF REJECTION**

**b.** Claims 41-47, 49-54, 58-73, 75-77 and 80-85 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the enablement requirement. The claims contain subject matter that was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention.

The claims are broadly drawn to a method of imparting pathogen resistance to plants by planting a seed transformed with a construct comprising a nucleic acid encoding a hypersensitive response elicitor (harpin) of SEQ ID NO:1, 3, 5, or 7 and a non-pathogen inducible promoter and propagating a plant from the seed or by transformation of a plant with the construct.

The instant specification, however, only provides guidance for methods of treating seeds of a number of plant species with SEQ ID NO:1, growing the plant, exposing it to one of a variety of plant pathogens, and observing that plants grown from treated seeds with more

pathogen resistant than plants grown from non-treated seeds (examples 1-8). The guidance related to expression of a nucleic acid encoding SEQ ID NO:1, 3, 5, or 7 in a plant is very general (specification, pg 36, line 6, to pg 37, line 12); however, plant transformation in general was well-known to those of skill in the art at the time of filing.

The instant specification fails to provide guidance for a method of imparting pathogen resistance to plants by planting a seed transformed with a construct comprising a nucleic acid encoding a hypersensitive response elicitor of SEQ ID NO:1, 3, 5, or 7 and a non-pathogen inducible promoter and propagating a plant from the seed or by transformation of a plant with the construct. Specifically, the specification fails to provide guidance for the use of a constitutive promoter in such constructs.

At the time of filing, constitutive expression of harpins in plants was considered lethal. For example, Bauer (US Patent 5, 850,015, filed June 1995) in discussing the expression in plants of a nucleic acid encoding the instant SEQ ID NO:1 states at column 13, lines 21-27:

Transformation of plants with the DNA molecule of the present invention is particularly useful where the plant does not exhibit a hypersensitive response to pathogens or is weakly responsive to such pathogens. This requires that *hrpN<sub>ech</sub>* be hooked up to the promotor of a plant gene that the pathogen induces such as PAL, CHS, etc. Otherwise, *hrpN* will kill the plant.

Beer et al (US Patent, 6,174,717, filed July 1992) expressed a similar belief that expression of HrpN would kill plant cells at column 24, lines 9-22):

Still another use would be the fusion of the gene encoding harpin to specific promoters of plant genes to develop specific transgenic plants. When the plant gene is "turned on", harpin would be expressed and the plant cell killed. Some appropriate plant gene promoters and their projected uses include genes involved in pollen development (resulting in the development of male sterile plants); genes that are expressed in response to infection by fungi, e.g. genes encoding phenylalanine ammonia lyase and chalcone synthase the plant cell would be killed thereby limiting the progress of the fungus and

making the plant resistant to fungal diseases); and genes involved in the development of senescence (to facilitate harvest, expression of *hrp* genes would result in defoliation).

It is noted that two of the inventors on this patent are two of the instant inventors, Steven Beer and Zhong-Min Wei.

This view was prevalent until 2000, 3 years after the filing of the parent of the instant application. Tampakaki et al (2000, *Molec. Plant Microbe Interact.* 13:1366-1374) initially expressed a harpin in plants using an inducible promoter because they “expect[ed] that endogenously produced harpin may be lethal to the plant” (pg 1367, left column, paragraph 4), but to their amazement found that even when large amounts of the biologically active harpin was constitutively produced in plants, the plants showed no necrosis (pg 1367, left column, paragraph 4, to pg 1369, left column, paragraph 1).

Thus, given the state of the art at the time of filing, one of skill in the art would not have expected a constitutive promoter to function in the instant invention because one of skill in the art would have expressed expression in a plant of a harpin from a constitutive promoter to kill the plant.

The instant specification makes no teaching as to the use of a constitutive promoter in expression of harpins in plants. Its only teaching with respect to plant promoters is the following on pg 36, lines 17-19:

As is conventional in the art, such transgenic plants would contain suitable vectors with various promoters including pathogen-induced promoters

Given the state of the art at the time of filing, use of non-inducible promoters would need to be taught by the specification.

The specification does not describe any working examples in which a plant was transformed with a construct comprising a nucleic acid encoding a hypersensitive response elicitor (harpin) of SEQ ID NO:1, 3, 5, or 7 and a non-pathogen inducible promoter.

Given the state of the art at the time of filing, the amount of direction provided by the inventor in the specification, and the lack of existence of working examples, the instant invention is not enabled.

#### **(10) Response to Argument**

a. Claims 41-47, 49-54, 58-73, 75-77 and 80-85 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement.

Appellant urges that it is clear from the recitation in the specification on pg 36, lines 17-21 that various promoters, including pathogen-resistant promoters, can be used in the claimed method; and that where pathogen-inducible promoters are an example of “various promoters”, the rest of the “various promoters” must be non-pathogen inducible ones (Brief, pg 5).

However, the art at the time of filing only contemplated that pathogen-inducible promoters would function in the claimed invention (see Bauer et al, Beer et al, and Tampakaki et al, as discussed in the 35 USC 112, 1<sup>st</sup>, enablement rejection above). As such, the instant specification would require explicit recitation of using non-pathogen inducible promoters in the claimed invention for support to be present.

Appellant urges that at the time of filing one of ordinary skill in the art was well aware of constitutive and other non-inducible or promoters for plant transformation, cites Koncs et al, Rogers '322, and Fraley '605, who all teach constitutive promoters, and concludes that they

constitute evidence that the instant application was intended to cover use of pathogen-inducible and non-pathogen-inducible promoters (Brief, pg 5-7).

However, at the time of filing, one of ordinary skill in the art would have expected that use of constitutive promoters in expression of a harpin in a plant would kill the plant, as detailed in the 35 USC 112, 1<sup>st</sup>, enablement rejection above. Thus, the instant specification would need to specifically mention constitutive promoters and/or other types of non-pathogen-inducible promoters for the instantly claimed invention to have been contemplated at the time of filing.

Appellant urges that the position that at the time of filing that the specification only contemplated the use of promoters in general or pathogen-inducible promoters is not consistent with the knowledge of those in skill in the art that promoters in general comprise pathogen-inducible promoters and non-pathogen inducible promoters (Brief, pg 7)

However, it is consistent with the knowledge of those in skill in the art at the time of filing that use of non-inducible promoters in expression of a harpin in a plant would kill the plant.

Appellant urges that the Examiner's position in the Advisory Action appears to be that the specification teaches only pathogen-inducible promoters and urges that nowhere in the specification is the claimed promoter limited to pathogen-inducible ones. (Brief, pg 7)

However, the Examiner's position in the Advisory Action in the advisory action is that no specific promoter type other than pathogen-inducible promoters is supported by the specification. Non-pathogen inducible promoters and constitutive promoters are induced in that.

**(11) Related Proceeding(s) Appendix**

No decision rendered by a court or the Board is identified by the examiner in the Related Appeals and Interferences section of this examiner's answer.

For the above reasons, it is believed that the rejections should be sustained.

This examiner's answer contains a new ground of rejection set forth in section (9) above. Accordingly, appellant must within **TWO MONTHS** from the date of this answer exercise one of the following two options to avoid *sua sponte dismissal of the appeal* as to the claims subject to the new ground of rejection:

(1) **Reopen prosecution.** Request that prosecution be reopened before the primary examiner by filing a reply under 37 CFR 1.111 with or without amendment, affidavit or other evidence. Any amendment, affidavit or other evidence must be relevant to the new grounds of rejection. A request that complies with 37 CFR 41.39(b)(1) will be entered and considered. Any request that prosecution be reopened will be treated as a request to withdraw the appeal.

(2) **Maintain appeal.** Request that the appeal be maintained by filing a reply brief as set forth in 37 CFR 41.41. Such a reply brief must address each new ground of rejection as set forth in 37 CFR 41.37(c)(1)(vii) and should be in compliance with the other requirements of 37 CFR 41.37(c). If a reply brief filed pursuant to 37 CFR 41.39(b)(2) is accompanied by any amendment, affidavit or other evidence, it shall be treated as a request that prosecution be reopened before the primary examiner under 37 CFR 41.39(b)(1).

Extensions of time under 37 CFR 1.136(a) are not applicable to the TWO MONTH time period set forth above. See 37 CFR 1.136(b) for extensions of time to reply for patent

applications and 37 CFR 1.550(c) for extensions of time to reply for ex parte reexamination proceedings.

Respectfully submitted,

Anne Kubelik

Primary Examiner

**A Technology Center Director or designee must personally approve the new ground(s) of rejection set forth in section (9) above by signing below:**

*George C. Elliott*  
George C. Elliott, Ph.D  
Director  
Technology Center 1600

Conferees:

Anne Marie Grunberg

*Anne Marie Grunberg*

Supervisory Patent Examiner, Art Units 1638 and 1661

Irem Yucel

Supervisory Patent Examiner, Art Unit 1636

*REMY YUCEL*  
REMY YUCEL, PH.D  
SUPERVISORY PATENT EXAMINER  
TECHNOLOGY CENTER 1600